



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Statement of Organization, Functions and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AN, Office of the Assistant Secretary for Preparedness and Response (ASPR), as last amended at 79 Fed. Reg. 70.535 (Nov. 26, 2014), 78 Fed. Reg. 25277 (April 30, 2013), 78 Fed. Reg. 7784 (Feb. 4, 2013), 75 Fed. Reg. 35.035 (June 21, 2010) to realign the functions of ASPR to reflect the changes mandated by the 21st Century Cures Act and to address ever-increasing manmade and naturally occurring threats which degrade public health, access to healthcare, access to emergency medical services and national security. The changes are as follows.

- I.** Under AN.10 Organization, delete all of the components and replace with the following:
 - A.** Immediate Office of the Assistant Secretary for Preparedness and Response (ANA)
 - B.** Office of Biomedical Advanced Research and Development Authority (ANB)
 - C.** Office of the Principal Deputy Assistant Secretary (ANC)
 - D.** Office of the Deputy Assistant Secretary Incident Command and Control (ANG)
- II.** Delete AN.20 Functions, in its entirety and replace with the following:

Section AR.20 Functions.

A. Immediate Office of the Assistant Secretary for Preparedness and Response:

The Immediate Office of the Assistant Secretary for Preparedness and Response (IO/ASPR) is headed by the Assistant Secretary, who provides leadership and executive and strategic direction for the ASPR organization. The Assistant Secretary is the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. The Assistant Secretary is responsible for carrying out ASPR's mission and implementing the functions of ASPR. The IO/ASPR (1) ensures development and maintenance of liaison relationships with HHS operating and staff divisions and represents HHS at interagency meetings, as required; (2) establishes and maintains effective communications and outreach guidance and support for all external communications, including legislative and executive branch questions and inquiries, and serves as the principal advisor to the ASPR on all legislative strategies to fulfill the Office of the ASPR and the HHS mission under section 2811 and other relevant sections of the Public Health Service Act, as amended; (3) oversees advanced research, development and procurement of qualified countermeasures, security countermeasures and qualified pandemic or epidemic products; (4) coordinate with relevant federal officials to ensure integration of federal preparedness and response activities for public health emergencies; (5) manages correspondence control for the Assistant Secretary; and (6) coordinates the strategic and operational activities for public health preparedness response and recovery.

B. Office of Biomedical Advance Research and Development Authority (ANB).

The Office of Biomedical Advanced Research and Development Authority (BARDA), established in April 2007 in response to the Pandemic and All-Hazards Preparedness Act of 2006, serves preparedness and response roles to provide medical countermeasures (MCM) in order to mitigate the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats and agents and emerging infectious diseases, including pandemic influenza.

BARDA executes this mission by facilitating research, development, innovation, and acquisition of MCM and expanding domestic manufacturing infrastructure and surge capacity of these MCM.

BARDA is headed by a Deputy Assistant Secretary, and includes the following components:

- Division of Influenza (ANB1)
- Division of Emerging Infectious Diseases (ANB2)
- Division of Chemical, Biological, Radiological and Nuclear Threats (ANB3)
- Division of Strategic Science and Technology (ANB4)
- Division of Regulatory and Quality Affairs (ANB5)
- Division of Research, Innovation and Ventures (ANB6)

C. Office of the Principal Deputy Assistant Secretary (ANC). The Office of the Principal Deputy Assistant Secretary (OPDAS) is responsible for providing a well-integrated infrastructure that supports the Department's capabilities to

prevent, prepare for, respond to and recover from natural public health and medical threats and emergencies. OPDAS leads the preparedness and response activities required to coordinate public health and healthcare response systems and activities with relevant federal, state, tribal, territorial, local, and international communities under the National Response Framework and Emergency Support Annexes #8, #6 and #14. OPDAS is responsible for the execution of business management operations and managing coordination. OPDAS provides for the facility, logistics, information technology and infrastructure support services necessary to maintain day-to-day operations of ASPR, including functions of Human Resources, Organization and Employee Development, Ethics, United States Public Health Service (USPHS) liaison, acquisitions management, contracts, grants, and all financial planning and analysis.

The Office of the Principal Deputy Assistant Secretary is headed by the Principal Deputy Assistant Secretary, and includes the following components:

- Division of Management Finance and Human Capital (ANC1)
- Division of Emergency Management and Medical Operations (ANC2)
- Division of Resource Management (ANC3)

D. Deputy Assistant Secretary Incident Command and Control (ANG): The Deputy Assistant Secretary (DAS/ICC) is responsible for the policy development, planning analysis, requirements and strategic planning. DAS/ICC manages and operates the HHS Secretary's Operation Center (SOC), intelligence, security,

information management and is also responsible for the HHS Continuity of Operations (COOP) and the development of the ASPR COOP Plan.

The Office of the Assistant Secretary Incident Command and Control (DAS/ICC) is headed by the Deputy Assistant Secretary Incident Command and Control, and includes the following components:

- Division of Security Intelligence and Information Management
- Division of Strategy, Policy, Planning and Requirements

III. Delegations of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Alex M. Azar II
Secretary

[FR Doc. 2018-15310 Filed: 7/17/2018 8:45 am; Publication Date: 7/18/2018]